

## Original Article

# Temporary Ileostomy Versus Temporary Colostomy: A Meta-analysis of Complications

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**OBJECTIVE:** To compare the complications of temporary diverting ileostomy with those of temporary colostomy for patients with colorectal diseases.

**METHODS:** Two independent researchers conducted a systematic search for randomized controlled trials (RCTs) comparing temporary ileostomy with temporary colostomy in MEDLINE, the Cochrane database, evidence-based medicine reviews and the American College of Physicians journal club, as well as relevant reference lists in journal articles. Five RCTs were found and included in this meta-analysis. All complications were abstracted and compared between groups. All complications were also assessed using tests of statistical heterogeneity, pooling of risk ratios using Mantel-Haenszel fixed effects and DerSimonian and Laird random effects. Clinical heterogeneity was investigated by examining the methodology and selection of patients described in each trial.

**RESULTS:** Temporary colostomy was significantly more likely to cause stoma complications in colorectal cancer patients undergoing elective resections, and also more likely to cause infectious and wound complications. Temporary ileostomy tended to cause more post-closure surgical complications.

**CONCLUSIONS:** There is not yet a strong case for the superiority of one temporary diverting stoma over another for all colorectal patients. In this regard, a large, well-conducted RCT is still needed. [*Asian J Surg* 2004;27(3): 202–10]

## Introduction

There is still controversy as to whether temporary (loop) transverse colostomy or temporary (loop) ileostomy is superior as a temporary faecal diversion for high-risk colorectal or colocolic anastomosis or other left-sided colonic diseases. Many observational studies as well as several small randomized controlled trials (RCTs) so far published to address this question have produced contradictory conclusions.<sup>1–11</sup> We conducted this overview of all published RCTs and performed a meta-analysis comparing the complications of these two temporary faecal diversion methods, to provide a more definitive answer to the above question. Clinically important heterogeneity between the RCTs was also examined, as well as the possible sources of this heterogeneity.

## Patients and methods

We conducted a systematic review of the published literature retrieved from the following databases: MEDLINE, the Cochrane database of systematic reviews, the Cochrane controlled trials register, evidence-based medicine reviews and the American College of Physicians journal club. All the papers identified in the search were further scrutinized for missed RCTs by checking their reference lists. There were no language restrictions and all published materials from the earliest entries in each of the databases were included in the search. Only RCTs comparing temporary ileostomy with temporary colostomy for faecal diversion in all types of colonic disease were selected. All relevant RCTs were included regardless of quality since very few have been published on this subject. Two re-

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searchers conducted the data search independently using the key words “ileostomy AND colostomy”, and “loop ileostomy AND loop colostomy”. Both researchers abstracted an identical set of five published RCTs.<sup>1-5</sup> The recorded characteristics of patients and of each trial included: total number of patients in each arm, central tendency for age, proportion of the sexes, indication for temporary enterostomy, proportion of cancer cases, length of time to stoma closure, and length of follow-up time after stoma closure. Outcomes of interest were the total number of patients with stoma-related complications, and all listed complications of temporary enterostomy both before and after stoma closure: complications related to the presence of a stoma and surgery-related complications. Meta-analysis was attempted for the total number of patients experiencing complications, as well as for each complication individually.

Outcomes of each trial were summarized as proportions and percentages of complications for both temporary colostomy and temporary ileostomy. Studies for which no particular outcome was available or that could not be explicitly expressed as risk ratios were excluded from the analysis for that particular outcome. Tests for statistical heterogeneity (or homogeneity tests) were based on the Mantel-Haenszel estimates.<sup>12</sup> Both Mantel-Haenszel fixed effects analysis and DerSimonian and Laird random effects analysis were used to

pool risk ratios of all the studies and calculate 95% confidence intervals (CI) for all outcomes of interest.<sup>12</sup> When statistical or clinical heterogeneity was detected or suspected, possible sources of this heterogeneity were investigated by comparing the methodology and patient characteristics across all trials.<sup>13</sup> There was no assessment of publication bias because there were too few RCTs.<sup>14</sup> User-written meta-analysis programmes in STATA (StataCorp, College Station, TX, USA) were used for all statistical analyses.<sup>15</sup> Statistically significant *p* values were set at 0.05 or lower.

## Results

Characteristics of each trial are given in Table 1. We will refer to each trial according to its number given in this table. Overall number and proportion of patients with the outcomes of interest are shown in Table 2. Individual complications are given in Tables 3 and 4 for the period prior to stoma closure and in Table 5 for the period after stoma closure. With the exception of the occurrence of post-closure enterocutaneous fistula (Table 5), all the complications listed in these tables were reported in at least three of the trials under review.

All trials were small, each with a sample size of less than 100 (Table 1). Patients in all trials were relatively old with similar central tendencies for age (> 60 years). Trial 3 was a multicen-

**Table 1.** Characteristics of each trial

Trial	Age, yr (range)		Male gender, <i>n</i> (%)		Colorectal cancer, <i>n</i> (%)		Days to stoma closure, median (range)		Indication for enterostomy	Follow-up duration
	IS	CS	IS	CS	IS	CS	IS	CS		
1. Queen Mary (2002) <sup>1</sup> <i>N</i> = 80	Mean: 65.2	Mean: 67.8	26/42 (61.9)	23/38 (60.5)	42/42 (100.0)	38/38 (100.0)	183	180	Low anterior resection for cancer	Not reported
2. North Hampshire (2001) <sup>2</sup> <i>N</i> = 70	Median: 63 (40–80)	Median: 68 (32–90)	27/34 (79.4)	22/36 (61.1)	33/34 (97.1)	35/36 (97.2)	62 (17–120)	73 (28–141)	Low anterior resection for cancer	Median 36 months after closure (range, 6–48)
3. Utrecht (1998) <sup>3</sup> <i>N</i> = 76	Mean: 63.2 (26–86)	Mean: 64.7 (29–83)	14/37 (37.8)	13/39 (33.3)	14/37 (37.8)	19/39 (48.7)	Usually 63–84 days		All at-risk colorectal surgery	12 months after closure
4. Royal Free (1987) <sup>4</sup> <i>N</i> = 61	Mean: 65 (46–86)	Mean: 65 (44–79)	23/32 (71.9)	13/29 (44.8)	27/32 (84.4)	24/29 (82.8)	15 (10–64)	19 (9–138)	All at-risk colorectal anastomosis	Not reported
5. Leeds (1986) <sup>5</sup> <i>N</i> = 47	Median: 71 (36–87)	Median: 66.5 (28–84)	11/23 (47.8)	12/24 (50.0)	20/23 (87.0)	18/24 (75.0)	77 (28–148)	87.5 (49–224)	Elective at-risk colorectal surgery	Up to 2.5 years after closure

IS = ileostomy group; CS = colostomy group.

trial that included younger patients, with a relatively low proportion of men. There appeared to be an important imbalance between the sexes in Trials 2 and 4, though for Trial 2 this might have been due to chance occurrence. In all but one trial (Trial 3), all or an overwhelming majority of patients had colorectal cancer. The time to closure of the stoma was highly variable, ranging from a relatively rapid closure after 2 or 3 weeks (Trial 4) to 6 months after stoma formation (Trial 1). Most trials were in elective surgical patients, except for Trials 3 and 4. In Trial 3, about half the patients in either arm underwent emergency surgery, while in Trial 4, all patients underwent temporary enterostomy to protect a high-risk colorectal anastomosis. Thus, Trial 3 had a more divergent set of patients. Finally, follow-up time after stoma closure appeared to vary considerably between the trials.

We defined “stoma complications” as any complication so defined by the authors of the trial (Table 2). In particular, the following were considered to be stoma complications: stoma prolapse, retraction, parastomal hernia, parastomal fistula, skin irritation due to leakage of intestinal contents and high stoma output with/without dietary modifications (Table 3). We explicitly excluded appliance leakage as a stoma complication since this was not a problem in recent trials.<sup>1,2</sup> All other complications that the authors tabulated in their studies, whether medical or surgical, were considered non-stoma complications. Among surgery-related non-stoma complications were hemorrhage, wound or infectious complications and intestinal obstruction (Table 4). Post-closure surgical complications were defined as complications arising after the closure of the temporary enterostomy that may need surgical

**Table 2.** Total number of patients with complications

Trial	Stoma complications <sup>a</sup> (%)		Pre-closure non-stoma complications <sup>a</sup> (%)		Post-closure surgical complications <sup>a</sup> (%)		Post-closure non-surgical complications <sup>a</sup> (%)		Perioperative deaths (%)	
	IS	CS	IS	CS	IS	CS	IS	CS	IS	CS
1 <sup>b</sup>	6/39 (15.4)	11/38 (28.9)	13/39 (33.3)	8/38 (21.1)	4/35 (11.4)	3/38 (7.9)	0/35	2/38 (5.3)	3/42 (7.1)	0/38
2 <sup>b</sup>	1/33 (3.0)	10/34 (29.4)	–	–	1/32 (3.1)	2/31 (6.5)	3/32 (9.4)	1/31 (3.2)	1/34 (2.9)	2/36 (5.6)
3 <sup>b</sup>	4/32 (12.5) <sup>c</sup>	0/38 <sup>c</sup>	5/32 (15.6)	1/38 (2.6)	7/29 (24.1)	3/32 (9.4)	1/29 (3.4)	0/32	5/37 (13.5)	1/39 (2.6)
4 <sup>b</sup>	3/31 (9.7) <sup>d</sup>	2/28 (7.1) <sup>d</sup>	8/31 (25.8)	8/28 (28.6)	1/31 (3.2)	1/28 (3.6)	–	–	1/32 (3.1)	1/29 (3.4)
5 <sup>b</sup>	3/17 (17.6) <sup>e</sup>	11/19 (57.9) <sup>e</sup>	–	–	6/20 (30.0) <sup>f</sup>	2/20 (10.0) <sup>f</sup>	–	–	3/23 (13.0)	4/24 (16.7)
M-H test for heterogeneity: <sup>g</sup> <i>p</i>	0.065 <sup>h</sup>		0.216		0.488		0.331		0.388	
M-H fixed effects summary: <sup>g</sup> pooled risk ratio (95% CI)	1.90 <sup>h</sup> (1.12–3.22) <sup>h</sup>		0.67 (0.40–1.44)		0.61 (0.31–1.20)		0.77 (0.21–2.84)		0.62 (0.27–1.43)	
Random effects summary: pooled risk ratio, (95% CI)	1.80 <sup>h</sup> (0.66–4.88) <sup>h</sup>		0.69 (0.33–1.44)		0.58 (0.28–1.20)		0.68 (0.13–3.52)		0.74 (0.29–1.91)	

<sup>a</sup> See definition of terms in the text.

<sup>b</sup> Study numbers and numbers of patients in each arm of each trial are shown in Table 1. Note that the denominator in the same trial varies; this depends on patients lost to follow-up or to postoperative death. Some cells are not filled because of lack of information.

<sup>c</sup> Patients with early stoma complications only.<sup>3</sup>

<sup>d</sup> The only occurring stoma complications explicitly counted, with the exception of appliance leakage, were peristomal skin irritation and parastomal fistula.

<sup>e</sup> Patients experiencing  $\geq 3$  stoma-related complications.<sup>5</sup>

<sup>f</sup> Three patients in the ileostomy and 1 patient in the colostomy group had early closure of their stoma.<sup>5</sup>

<sup>g</sup> M-H test and summary: Mantel-Haenszel test for heterogeneity and summary statistics.

<sup>h</sup> In Trial 3, M-H test  $p = 0.252$ , the fixed effect risk ratio is 2.7 (95% CI, 1.48–4.95) and the random effects risk ratio is 2.5 (95% CI, 1.13–5.52).

IS = ileostomy; CS = colostomy; M-H = Mantel-Haenszel.

**Table 3.** Stoma-related pre-closure complications

Trial	Prolapse, <i>n</i> (%)		Parastomal fistula, <i>n</i> (%)		Parastomal hernia, <i>n</i> (%)		High output/ dietary change, <i>n</i> (%)		Skin irritation, <i>n</i> (%)	
	IS	CS	IS	CS	IS	CS	IS	CS	IS	CS
1	0/39	3/38 (7.9)	-	-	1/39 (2.6)	0/38	1/39 (2.6)	0/38	4/39 (10.3)	7/38 (18.4)
2	0/33	2/34 (5.9)	0/33	1/34 (2.9)	0/33	2/34 (5.9)	1/33 (3.0)	0/34	-	-
3	1/32 (3.1)	16/38 (42.1)	1/32 (3.1)	2/38 (5.3)	2/32 (6.3)	0/38	23/32 (71.9)	4/38 (10.5)	11/32 (34.4)*	9/38 (23.7)*
4	0/31	0/28	1/31 (3.2)	1/28 (3.6)	-	-	-	-	2/31 (6.5)	1/28 (3.6)
5	1/17 (5.9)	4/19 (21.1)	-	-	-	-	-	-	7/17 (41.2)	9/19 (47.4)
M-H test for heterogeneity: <i>p</i>	0.819		0.902		0.264		0.804		0.504	
M-H fixed effects summary: pooled risk ratio (95% CI)	7.77 (2.41–25.03)		1.71 (0.37–7.91)		0.73 (0.19–2.86)		0.17 (0.07–0.40)		0.99 (0.62–1.58)	
Random effects summary: pooled risk ratio (95% CI)	6.79 (2.02–22.16)		1.68 (0.36–7.92)		0.67 (0.09–5.11)		0.17 (0.07–0.40)		0.98 (0.62–1.57)	

\*Patients requiring treatment only. IS = ileostomy; CS = colostomy; M-H = Mantel-Haenszel.

**Table 4.** Other pre-closure complications and events

Trial	Colonic anastomosis leakage, <i>n</i> (%)		Wound/ infectious complications, <i>n</i> (%)		Intestinal obstruction, <i>n</i> (%)		Appliance leakage, <i>n</i> (%)		Non-closure, <i>n</i> (%)	
	IS	CS	IS	CS	IS	CS	IS	CS	IS	CS
1	2/39 (5.1)	2/38 (5.3)	-	-	3/39 (7.7)	0/38	-	-	4/39 (10.3)	0/38
2	2/33 (6.1)	1/34 (2.9)	-	-	-	-	-	-	2/33 (6.1)	2/34 (5.9)
3	-	-	0/32	1/38 (2.6)	-	-	12/32 (37.5)	18/38 (47.4)	2/31 (6.5)	2/34 (5.9)
4	2/31 (6.5)	6/28 (21.4)	3/31 (9.7)	4/28 (14.3)	2/31 (6.5)	3/28 (10.7)	21/31 (67.7)	17/28 (60.7)	-	-
5	5/19 (26.3)	6/20 (30.0)	3/20 (15.0)	8/18 (44.4)	2/23 (8.7)	2/23 (8.7)	3/17 (17.6)	6/19 (31.6)	0/20	0/20
M-H test for heterogeneity: <i>p</i>	0.517		0.754		0.354		0.374		0.401	
M-H fixed effects summary: pooled risk ratio (95% CI)	1.37 (0.68–2.79)		2.25 (0.96–5.28)		0.77 (0.27–2.22)		1.11 (0.81–1.52)		0.51 (0.17–1.58)	
Random effects summary: pooled risk ratio (95% CI)	1.32 (0.64–2.75)		2.25 (0.95–5.34)		0.92 (0.28–3.0)		1.04 (0.76–1.41)		0.65 (0.19–2.18)	

IS = ileostomy; CS = colostomy; M-H = Mantel-Haenszel.

**Table 5.** Post-closure surgical complications

	Surgical site infection, <i>n</i> (%)		Enterocutaneous fistula, <i>n</i> (%)		Intestinal obstruction and ileus, <i>n</i> (%)	
	IS	CS	IS	CS	IS	CS
1	1/35 (2.9)	2/38 (5.3)	1/35 (2.9)	0/38	3/35 (8.6)	1/38 (2.6)
2	1/32 (3.1)	2/31 (6.5)	-	-	0/32	1/31 (3.2)
3	2/29 (6.9)	1/32 (3.1)	2/29 (6.9)	1/32 (3.1)	2/29 (6.9)	1/32 (3.1)
4	-	-	-	-	-	-
5	0/20	6/20 (30.0)	-	-	2/20 (10.0)	0/20
M-H test for heterogeneity: <i>p</i>	0.331		0.847		0.610	
M-H fixed effects summary: pooled risk ratio (95% CI)	2.47 (0.86–7.09)		0.39 (0.06–2.56)		0.48 (0.15–1.54)	
Random effects summary: pooled risk ratio (95% CI)	1.91 (0.52–7.06)		0.40 (0.06–2.60)		0.47 (0.13–1.71)	

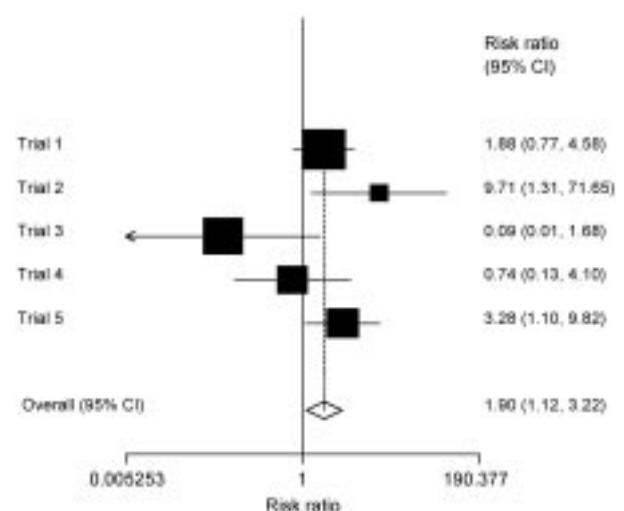
IS = ileostomy; CS = colostomy; M-H = Mantel-Haenszel.

treatment or arising directly from the surgical procedure. Among such complications were surgical site infection, intestinal obstruction and enterocutaneous fistula (Table 5). Post-closure non-surgical complications were mostly medical complications. These included pneumonia, deep vein thrombosis, pulmonary embolism, respiratory insufficiency, cardiac arrhythmia, myocardial infarction and urinary retention.

Although all trials reported some form of stoma complication, not all were reported in the same way. Trials 1, 2 and 4 reported the total number of patients with some form of stoma complication arising throughout the period prior to stoma closure, while in Trial 3, this number was reported for early stoma complications only, and in Trial 5, this was reported for patients with three or more stoma complications. Under the assumption that comparing these numbers represented a valid comparison of overall stoma complications, we pooled the risk ratios of stoma complications for temporary colostomy over those of temporary ileostomy for all five trials. The heterogeneity test was of borderline significance ( $p = 0.065$ ). The pooled fixed effects Mantel-Haenszel estimate of the overall risk ratio showed a 90% increase in stoma complications for temporary colostomy over that for ileostomy, a statistically significant result. The random effects analysis showed a smaller, and non-significant, increase of 80%,

with a markedly wider 95% CI. Trial 3 appeared to be an important outlier here (Figure 1).

A pooling of post-closure surgical complication risk ratios revealed no evidence of statistical heterogeneity ( $p = 0.488$ ) (Figure 2). The fixed effects and random effects pooled risk ratios were very similar, with approximately 40% reduction in complications for colostomy patients, but this was not statis-



**Figure 1.** Forest plot of all trials reporting risk of stoma complications. Trial 3 is different to other trials. The pooled risk ratio ("overall") was calculated using the Mantel-Haenszel fixed effects method. 95% CI = 95% confidence interval.

tically significant. A similar tendency was seen for pre-closure non-stoma complications, post-closure non-surgical complications and operative deaths, none of which were statistically significant.

Stoma prolapse was significantly more common in the colostomy group (no significant heterogeneity between studies), with a pooled increased risk of almost eight times that of the ileostomy group (Table 3). High stomal output was significantly more common in the ileostomy group (6 times more common), with the same trend for all trials. However, Trial 3 overwhelmingly dominated this outcome. Only one trial provided information on stoma retraction (Trial 3: more common for ileostomies; risk ratio, 0.21; 95% CI, 0.02–1.79). Parastomal fistula tended to occur more commonly in the colostomy group, though without statistical significance. There appeared to be a lower risk of parastomal hernia in the colostomy group, but this was not statistically significant. No trend was evident for skin irritation caused by the presence of a stoma.

There was a slightly higher but non-significant risk of colonic anastomosis (defined as coloanal or colocolic anastomosis) leakage in the colostomy group (almost 40% increase, without significant between-study heterogeneity) (Table 4). Wound and infectious complications were twice as common in the colostomy group, a marginally significant result on both fixed effects and random effects analyses (with no evidence for heterogeneity). No significant difference was shown in the risk of gut obstruction, in the occurrence of

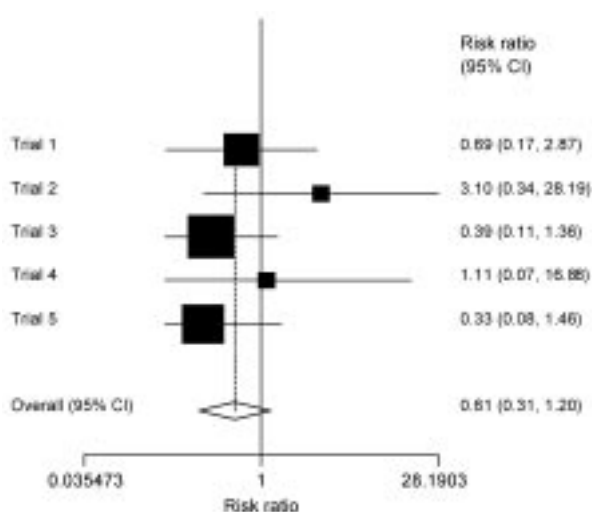
appliance leakage, and the rates of non-closure of stoma between the two groups.

There seemed to be a tendency for more surgical site infections in the colostomy group, with slight evidence of heterogeneity ( $p = 0.331$ ) with considerable difference between the fixed effects and random effects estimates, but these studies were dominated by Trial 5 (Table 5). Only two trials contributed to the calculation of the pooled risk ratio of enterocutaneous fistula following stoma closure, and there were few such outcomes in each trial. The difference was thus not statistically significant. There was a common tendency for a higher risk of gut obstruction or ileus in the ileostomy group (twice as common), although this was also not statistically significant.

## Discussion

In this study, we compared the complications of temporary ileostomy with those of temporary colostomy, when used for protecting high-risk colonic anastomosis or for certain colorectal conditions, in the context of a systematic review and meta-analysis. When all trials were included in the analysis, several specific complications were significantly more common for one type of stoma than the other, but the overall number of complications did not clearly differ between the two.

There was an increased risk of stoma complications in the colostomy group for three trials (Trials 1, 2 and 5) and a decreased risk in Trials 3 and 4 (Table 2, columns 2 and 3). The main outlier was Trial 3 (Figure 1). There appeared to be important heterogeneity between the trials, and the most important source can be found in Trial 3. We interpreted borderline significant heterogeneity as important, since heterogeneity tests are known to lack statistical power.<sup>12</sup> Patients in that trial included emergency cases as well as conditions that might be associated with difficult stoma construction (i.e. intra-abdominal infection and ileus), which may partly explain the peculiar difference in stoma complications between the two types of stoma, as well as the relatively high frequency of these complications (e.g. more stoma prolapse and retraction, and more cases with skin irritation or appliance leakage). Therefore, it might not be valid to include Trial 3 in a pooled estimate on the basis of difference in reporting (thus compromising the similarity of patients being pooled) and the fact that half the sample comprised non-cancer cases. By excluding Trial 3 from the analysis of overall stoma complications, we found that between-trial heterogeneity was no longer so significant, and the pooled risk ratio of the four



**Figure 2.** Forest plot of all trials reporting risk of post-closure surgical complications. Trial 2 lies further away from other studies, but its influence is low. Thus, there is not much evidence of between-trial heterogeneity. The pooled risk ratio was calculated using the Mantel-Haenszel fixed effects method. 95% CI = 95% confidence interval.

remaining trials increased to 2.7 (95% CI, 1.48–4.95) for the fixed effects analysis and 2.5 (95% CI, 1.13–5.52) for the random effects analysis, both of which are statistically significant. We may therefore conclude that overall stoma complications were more frequent for colostomies, when performed electively, and for colorectal cancer. On the other hand, for patients undergoing emergency or non-cancer colonic surgery, there may be a tendency for more stoma complications in the ileostomy group (Trial 3).

Looking at the stoma complications in more detail (Tables 3 and 4), we found that ileostomy was clearly superior to colostomy in terms of stoma prolapse, even if Trial 3 was excluded, while no clear advantage could be seen in terms of peristomal fistula, parastomal hernia, skin irritation or appliance leakage for either type of stoma. High-output stoma was an important problem for ileostomies, however, but this was not significant if Trial 3 was excluded. We may conclude that stoma prolapse was the only stoma complication clearly shown to be more frequent in the colostomy group, for elective colorectal cancer patients. On the other hand, for patients undergoing emergency or non-cancer colonic surgery, there may be significantly higher risk of ileostomies becoming high-output stomas (Trial 3).

In terms of non-stoma complications, wound and infectious complications were considerably more frequent in the colostomy group (more than twice as common, Table 4). Trial 3 reported results in conformity with other trials. Pre-closure gut obstruction was more common in the ileostomy group, a result similar to other studies but not statistically significant.<sup>1,6</sup> Leakages in colonic anastomoses and risk of non-closure of the stoma were not significantly different between the two groups. We conclude that wound and infectious complications were the only non-stoma complications shown to differ substantially between the two stomas, with higher risk for colostomies.

Post-closure surgical complications reported as total number of patients experiencing these complications were available for all trials (Table 2). There was no statistical difference between the two groups, but there was a trend towards fewer complications in the colostomy group. Essentially similar conclusions were reached after excluding Trial 3. Specific post-closure surgical complications were not clearly reported for Trial 4 (Table 5), and since the occurrence of these complications was relatively rare, statistical significance was also not achieved for any one of these complications (Table 5). In particular, occurrence of intestinal obstruction or ileus was not clearly different between the two groups, although there

was a tendency for more frequent occurrence in the ileostomy group. Surgical site infection had a tendency to occur more often in the colostomy group, as in the pre-closure period, and this might be due to the nature of microbial flora in the stoma.<sup>2,5</sup>

It may be noted that there was apparently no logical association between the frequency of complications recorded and length of follow-up (i.e. cumulative incidence), either during the period prior to stoma closure or the period thereafter. For example, Trial 4 with short pre-closure follow-up reported a higher incidence of non-stoma complications than Trial 1 with much longer pre-closure follow-up; we would have expected the reverse to be true.<sup>2</sup> This could reflect important differences in case selection and the definition or detection of complications between trials (see below).

Similarly, no systematic differences in the frequency of any complications were seen between earlier trials (Trials 4 and 5) and trials performed 10 or more years later (Trials 1, 2 and 3), not even for appliance leakage (which should be less of a problem now).<sup>2</sup> Again, differences in case selection and definitions of various complications could be the major reason.

As in many systematic reviews and meta-analyses, this study encountered several methodological problems.<sup>16</sup> These limitations must be considered if the results of this study are to be appropriately interpreted. First of all, the number of trials included in this review was rather small. This was compounded by the fact that all the studies also contained small numbers of patients and some complications did not occur frequently. Thus, in most instances, the number of pooled patients was still inadequate for a powerful analysis.

Secondly, the selection of patients was different for each trial, with the possible exception of Trials 1 and 2, in which both sets of patients were restricted to elective cases undergoing total mesorectal excision and low anterior resection. In one case (Trial 3), the selected group of patients differed markedly from that in other trials. This was the main evidence for clinical heterogeneity between trials. However, this heterogeneity may, in fact, be a strength of a meta-analysis if there was no statistical heterogeneity between the outcomes: this is because the results may be pooled and, thus, a single result can be obtained that will be applicable to a wide variety of patients (i.e. the results will be more generalizable, although this point is controversial).<sup>13</sup> Unfortunately, clinical heterogeneity often implies statistical heterogeneity,<sup>13</sup> as was the case in this study.

Thirdly, information was lacking on the conduct of the trials (except for a brief description of randomization in Trial 4) and the definitions of the relevant outcomes. This meant

that randomization might have been inadequate in some trials (e.g. there was a marked imbalance of male/female patients between the two arms in Trial 4), the assessment of outcomes might have been biased (cannot ensure impartial assessment), and some of the complications recorded might have had different meanings in different trials (there might be disagreement in the definitions of outcomes). Treatment was different between trials (surgical techniques were different, as well as expertise). The differing lengths of follow-up implied differing cumulative incidences, as mentioned above. Finally, a considerable amount of information was missing on some of the complications (empty cells in the tables); we cannot determine how this would influence our results (besides loss of statistical power).

All these problems limit the possibility and validity of combining trial outcomes, although, since the comparisons were made within trials, if the contrasts were similar enough (e.g. no statistical heterogeneity), an argument may be made for assuming that a single outcome can represent all trials. Individual patient data meta-analysis might provide more information than a meta-analysis of summary results,<sup>13</sup> in particular when comparing the total number of patients with all complications both before and after stoma closure, or other comparisons not possible in this analysis. This overview therefore strongly points towards a need for a much larger, well-conducted RCT (with standardized definition of outcomes) to help definitively settle the question of stoma superiority, since current evidence is weak either way. There is, however, some evidence favouring ileostomy in terms of stoma complications (especially stoma prolapse) and wound or infectious complications in colorectal cancer patients undergoing elective resections. A recent large retrospective study comparing stoma complications reached a similar conclusion.<sup>7</sup> Other studies to be conducted in the future should also include other outcome measures, such as quality of life (as for Trial 3 in a later publication),<sup>17,18</sup> technical difficulty and cost-effectiveness, since operative complications are not the only outcomes of interest. For example, only two trials (Trials 2 and 5) attempted to directly measure technical difficulty in stoma construction or closure, but they used different measures. Both trials, as well as anecdotal reports in others (Trials 1 and 3), seemed to consistently show that closure of a loop colostomy was an easier procedure. Taking these other outcomes into account may possibly change the surgeon's or the patient's preference.<sup>6</sup> Finally, we may need to ask ourselves whether or how another large trial will benefit patient care. Instead of regarding these stomas as competing options, it may be more appro-

priate to regard them as complementary, with their own usefulness in specific situations.<sup>2,5-7</sup> If trials are to be conducted in the future, subgroups of patients, such as emergency colorectal patients, may need to be investigated in detail and explicitly included in the design.

## Conclusions

We performed a meta-analysis of all RCTs that compared complications of temporary ileostomy and those of temporary colostomy for patients with all types of colorectal disease. Five trials were reviewed. Stoma complications were more frequent for colostomy performed in colorectal cancer patients undergoing elective surgery, almost threefold higher. Most significant of these complications was stoma prolapse. Pre-closure infectious and wound complications were also more frequent (twofold higher) in the colostomy group. Since there was only one trial with a substantial proportion of emergency and non-cancer patients (Trial 3), we cannot reach any definite conclusions for this subset of patients. Although there was a tendency for more complications after closure of the stoma in the ileostomy group, this was not statistically significant.

There was important (statistical and clinical) between-trial heterogeneity, notably due to case selection. In most instances, only one trial (Trial 3) contributed outlying results, and removal of this trial significantly decreased between-trial heterogeneity, at the price of limiting generalizability. Other potentially important problems were questionable quality of trial design and conduct, non-standardized outcome definitions, differences in follow-up time, and lack of other relevant outcomes of interest. Overall, the meta-analysis still lacked power for some complications of interest because of the small pooled sample size (total number of patients = 334) and relative rarity of the outcomes.

A strong case for superiority of one temporary diverting stoma over another for all colorectal cancer patients cannot yet be made. A large, well-conducted RCT will be needed in this regard. More likely, both temporary colostomy and temporary ileostomy will become complementary diversion methods (e.g. with their own usefulness in different subgroups of patients), rather than competitors.

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